50. (New) An isolated or purified CILP encoded by SEQ ID NO:1.

51. (New) An isolated or purified CILP having a molecular mass of 92,000, wherein said CILP binds to at least one antibody raised against a CILP encoded by SEQ ID NO:1.

52. (New) The CILP of claim 51, wherein said CILP is a human CILP.

53. (New) The CILP of claim 51, wherein said CILP is a cow CILP.

54. (New) The CILP of claim 51, wherein said CILP is a dog CILP.

55. (New) The CILP of claim 51, wherein said CILP is a horse CILP.

56. (New) An isolated or purified peptide consisting of the sequence of residues 1-682 of SEQ ID NO:2.

REMARKS

By this Amendment, claims 2, 7-17, and 19-35 are cancelled, claims 1 and 3 are amended, and new claims 36-56 are added. New claims 36-56 are directed to elected Group I and/or re-joined Groups II and III. Exemplary support for the amendments to claims 1 and 3, and for new claims 36-56, comes from the specification, as originally filed, as follows:

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Claim	Support in Specification
1, 56	page 3, lines 10-11; page 43, lines 8-13
3	page 6, lines 5-12; Figure 1; page 12, lines 1-3
36	page 3, lines 10-11
37	page 4, lines 7-9
38	page 3, lines 10-11; page 10, line 22 through page 11, line 3; page 43, lines 8-21; Figure 1
39	page 11, line 3
40	page 11, lines 4-5
41, 42	page 11, line 5
43	page 11, lines 5-6
44	page 11, line 6
45	page 44, lines 15-17; page 45, lines 15-16; page 25, line 17 through page 26, line 2; Figures 1 and 6
46-48	page 42, line 22 through page 43, line 1; page 44, lines 14-15; page 11, lines 3-6
49	page 43, lines 8-21
50	Figure 8; page 16, line 21 through page 17, line 2
51	page 43, lines 8-21; Figure 1
52-55	Figure 1; page 12, lines 1-3; page 27, line 18 through page 28, line 18

Accordingly, no new matter is added. Currently, claims 1, 3-6, 18, and 36-56 are pending in this application.

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I. *Restriction Requirement*

The Office withdraws the Restriction Requirement with regard to Groups I-III, and makes the Requirement FINAL with regard to the other Groups. (Office Action at paragraph 2.) Applicants thank the Examiner for rejoinder of Groups II and III with elected Group I. Applicants respectfully request that the Office reconsider the Restriction Requirement with regard to claim 18, which recites a recombinant cell comprising the peptide of claim 1. Applicants respectfully submit that claim 18 is directed to the same invention as claim 1, and thus should be examined in this application.

II. *Drawings*

The Office indicates that the drawings are improper. (Office Action at paragraph 5.) Applicants are preparing new formal drawings that satisfy the requirements of 37 C.F.R. §§ 1.84 and 1.152, and will submit them before issuance of this application as a U.S. Patent. Applicants respectfully request that the Office hold the objection to the drawings in abeyance pending submission of the new formal drawings.

III. *Rejection Under 35 U.S.C. § 112, second paragraph*

The Office rejects claims 1 and 7 as indefinite for reciting "at least one antibody". (Office Action at paragraph 10.) By this Amendment, claim 7 is cancelled, rendering the rejection as it applies to that claim moot. Applicants respectfully traverse the rejection as it applies to claim 1 and as it might be applied to new claims 38 and 51 (which recite "at least one antibody"). The

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phrase "at least one antibody" is used in the present claims to indicate that the claims relate to both monoclonal antibodies, polyclonal antibodies, and mixtures of monoclonal and/or polyclonal antibodies. It is known in the art that a composition (*e.g.*, serum) comprising polyclonal antibodies can include more than one different type of antibody (*e.g.*, different classes of antibodies and antibodies with different epitope specificities). Furthermore, it is evident that a mixture of multiple antibodies or antibody preparations raised against CILP can comprise more than one type of antibody. In view of these facts, Applicants believe that a claim reciting "an antibody" could be misinterpreted as excluding polyclonal antibodies or mixtures of antibody preparations. That is, "an antibody" could be interpreted as meaning "one antibody", which could exclude polyclonal antibodies or mixtures of antibody preparations. Excluding these antibodies and antibody preparations is not Applicants' intent. Therefore, Applicants have used the phrase "at least one antibody" to clearly indicate that one or more antibody that binds to CILP can be present.

In view of the claim language and the intent of Applicants, as explained above, Applicants respectfully submit that the phrase "at least one antibody" is clear and definite. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 1 under 35 U.S.C. § 112, second paragraph.

IV. *Rejections Under 35 U.S.C. § 112, first paragraph*

A. Scope of Enablement

The Office rejects claims 1-8, 23, 24, and 35 under 35 U.S.C. § 112, first paragraph, as not enabled for the full scope of the claims. Specifically, the Office asserts that the specification

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does not enable the use of *any* CILP, analog, homolog, or fragment for treating an individual suffering from joint disease, or for pharmaceutical compositions. (Office Action at paragraph 7.) By this Amendment, claims 2, 7, 8, 23, 24, and 35 are cancelled, rendering the rejection moot as it applies to those claims. Applicants respectfully traverse the rejection as it applies to claims 1 and 3-6, and as it might be applied to new claims 36-56.

The presently pending claims do not recite pharmaceutical compositions or methods of treating individuals for diseases. Claims directed to that subject matter have been cancelled or amended so that they no longer recite such subject matter. Applicants expressly reserve the right to prosecute that subject matter in continuation applications.

As the Office recognizes, the claimed CILP, analogs, and fragments can be used to produce antibodies that can be used in detection assays. (Office Action at paragraph 7, page 2.) Because the claims no longer recite pharmaceutical compositions or methods of treating individuals, and because the specification teaches one of skill in the art how to make and use the claimed CILP, analogs, and fragments to raise antibodies for detection assays, the present claims are fully enabled by the specification.

Accordingly, Applicants respectfully request that the Office reconsider and withdraw the rejection of claims 1 and 3-6 under 35 U.S.C. § 112, first paragraph, as not enabled by the specification for the full scope of the claims.

B. Written Description

The Office rejects claims 1-8, 23, 24, and 35 under 35 U.S.C. § 112, first paragraph, as containing subject matter that is not supported by an adequate written description in the

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specification. Specifically, the Office asserts that because the specification does not provide the specific amino acid sequences of *all* CILP proteins, *all* CILP analogs, and *all* immunoreactive fragments of CILP, its analogs and homologs, there is not an adequate written description of the claimed invention. (Office Action at paragraph 8.) By this Amendment, claims 2, 7, 8, 23, 24, and 35 are cancelled, rendering the rejection moot as it applies to those claims. Applicants respectfully traverse the rejection as it applies to claims 1 and 3-6, and as it might be applied to new claims 36-56.

The Office bases its rejection solely on the holding in *University of California v. Eli Lilly and Co.* and the Revised Interim Guidelines for the Examination of Patent Applications Under 35 U.S.C. 112, first paragraph (the Interim Guidelines were published in December of 1999). Based on its interpretation of this case and the Interim Guidelines, the Office concludes that Applicants were not in possession of the full scope of the claims because the sequence of only the human CILP and certain fragments of it are specifically disclosed in the present application. Applicants respectfully submit that, although *Lilly* is currently valid law with regard to the written description requirement of 35 U.S.C. § 112, first paragraph, its holding does not control the present situation. Furthermore, Applicants respectfully submit that the current Written Description Guidelines (published January 5, 2001, in Vol. 66, No. 4, of the Federal Register) clearly indicate that the present claims are supported by an adequate written description. Therefore, Applicants respectfully submit that the present claims satisfy the written description requirement of 35 U.S.C. § 112, first paragraph.

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Applicants respectfully submit that the present situation is factually distinguishable from that of *Lilly*, and thus, *Lilly* does not control whether the present claims are adequately described by the specification. In *Lilly*, the patentee (University of California) had cloned and sequenced a single gene, the rat insulin gene. However, its patent claims encompassed *all* vertebrate and mammalian insulin genes. The Federal Circuit found that claims encompassing insulin genes other than the rat gene were not supported by an adequate written description because no sequence *or other relevant structural or physical characteristics* were disclosed in the specification to show that the applicants were in possession of the claimed invention at the time of filing of the application. (*Regents of the University of California v. Eli Lilly & Co.* 119 F.3d 1559, 1567 (Fed. Cir. 1997).)

Unlike the University of California, which presented *no* information relating to vertebrate or mammalian insulin genes other than the rat gene, the present Applicants have clearly shown that, at the time of filing of this application, they were in possession of not only the human CILP, but the cow CILP, dog CILP, and horse CILP as well. In particular, as can be seen from Figure 1 and the accompanying text on page 6, lines 5-12, and page 27, line 18 through page 28, line 22, Applicants at least partially purified the CILP from not only human tissue, but cow, dog, and horse tissue as well. The specification and Figure 1 clearly indicate that the CILP from each species is the same molecular weight and binds to polyclonal antibodies raised against the human CILP. Thus, unlike the patent specification in *Lilly*, the present specification provides clear evidence that Applicants were in possession of multiple CILP proteins according to the claims at the time of filing of this application.

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Furthermore, the current Guidelines for Examination of Patent Applications under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement clearly indicate that *Lilly* does not lay down a *per se* requirement for disclosure of sequence information in order to adequately describe a nucleic acid or protein. Rather, an adequate description is provided by "describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention." (See footnote 8 of the Guidelines, citing *Amgen Inc. v. Chugai Pharmaceutical*; page 1105, right column; and page 1106, left column.) A key identifying characteristic of a protein, which shows possession of the protein by the applicant, is the protein's ability to cross-react with a known antibody. (See footnote 42 of the Guidelines.) Finally, footnote 36 states that actual reduction to practice (as is the case in the present application) is the best evidence of completion of the invention, and thus of an adequate written description. Indeed, according to the Guidelines, the "fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed." (Guidelines, page 1105, center column.)

In *Lilly*, the Federal Circuit concluded that the University of California was not in possession of any insulin gene other than that of the rat because the patent specification provided absolutely *no* distinguishing identifying characteristics, such as a nucleic acid sequence, that was sufficient to show that the applicant was in possession of the claimed invention at the time of filing of the application. In contrast, the present application clearly shows that Applicants were in possession of not only the human CILP, but the cow, dog, and horse CILP as well. Therefore, the present claims directed to CILP are supported by an adequate written description, and

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Applicants respectfully request that the Office reconsider and withdraw the rejection of claim 1 under 35 U.S.C. § 112, first paragraph, as failing to be supported by an adequate written description.

V. *Rejections Under 35 U.S.C. § 102*

A. Lorenzo *et al.*

The Office rejects claims 1-8 under 35 U.S.C. § 102(b) as anticipated by Lorenzo *et al.* (Office Action at paragraph 12.) By this Amendment, claims 2, 7, and 8 are cancelled, rendering the rejection moot as it applies to those claims. Applicants respectfully traverse this rejection as it applies to claims 1 and 3-6, and as it might be applied to new claims 36-56. Applicants respectfully submit that Lorenzo *et al.* is not prior art against the claims under 35 U.S.C. § 102.

Initially, Applicants submit that Lorenzo *et al.* does not qualify as prior art under 35 U.S.C. § 102(b). The present application claims the benefit of the filing date of U.S. Provisional application Serial No. 60/142,054, filed July 2, 1999. Lorenzo *et al.* was published September 4, 1998, which is less than one year before the filing date of U.S. Provisional application Serial No. 60/142,054. Therefore, Lorenzo *et al.* does not qualify as prior art under 35 U.S.C. § 102(b). In an effort to expedite prosecution of this application, Applicants will respond to the rejection as if it had been set forth under 35 U.S.C. § 102(a).

Applicants respectfully submit that Lorenzo *et al.* does not qualify as prior art under 35 U.S.C. § 102(a) because the relevant portions of Lorenzo *et al.* originated with Applicants, and describe Applicants' own work.

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Attached hereto is a Declaration Under 37 C.F.R. § 1.132 of one of the Applicants, Dr. Dick Heinegård. The Declaration states that Peter Neame and Yngve Sommarin, who are the second and third authors, respectively, of the Lorenzo *et al.* reference, did not make an inventive contribution to the invention of claims 1, 3-16, 18, and/or 36-56 of the present application. Dr. Heinegård states that these men were either under his direct supervision and/or merely provided technical assistance in confirming the identity of a peptide of a CILP protein according to the present invention.

Thus, the relevant portions of Lorenzo *et al.* describe the inventive contributions of Dr. Heinegård and Dr. Lorenzo only. The disclosure of Applicants' own work less than one year before the filing date of an application for a U.S. patent cannot be used against the Applicants under 35 U.S.C. § 102(a). *In re Katz*, 687 F.2d 450, 215 U.S.P.Q. 14 (CCPA 1982). *See, also,* MPEP § 2132.01. Therefore, Lorenzo *et al.* cannot be used under 35 U.S.C. § 102(a) against the present claims.

In view of the attached Declaration under 37 C.F.R. § 1.132 of Dr. Heinegård, Applicants respectfully submits that Lorenzo *et al.* is not prior art under 35 U.S.C. § 102(a). For at least this reason, Applicants respectfully requests reconsideration and withdrawal of the rejection of claims 1 and 3-6 as anticipated by Lorenzo *et al.*

B. Masuda *et al.*

The Office rejects claims 1, 2, and 4-7 under 35 U.S.C. § 102(b) as anticipated by Masuda *et al.* (Office Action at paragraph 13.) By this Amendment, claims 2 and 7 are cancelled, rendering the rejection moot as it applies to those claims. Applicants respectfully

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traverse the rejection as it applies to claims 1 and 4-6, and as it might be applied to new claims 36-56.

Masuda *et al.* discloses the porcine (pig) chondrocyte nucleotide pyrophosphohydrolase (NTPPHase). It is produced as part of an insoluble 127 kDa protein that is cleaved to release a soluble 61 kDa protein having the pyrophosphohydrolase activity. (Masuda *et al.* at page 278, left column; page 284, right column.) The nucleotide and amino acid sequences of the NTPPHase are disclosed in Figure 2 (page 282). Masuda *et al.* also disclose an antibody that was raised against an N-terminal peptide from the 61 kDa protein. However, Masuda *et al.* does not disclose or suggest a CILP protein, analogs of a CILP protein, or fragments of a CILP protein that are immunoreactive with at least one antibody that is specific for a CILP protein.

Masuda *et al.* discloses that the porcine NTPPHase is expressed as part of a pre-protein of 127 kDa, which includes the NTPPHase and another uncharacterized protein. As disclosed in the present specification, CILP is expressed as part of a pre-protein of 132.5 kDa. The pre-protein comprises both the CILP and a NTPPHase. (See, for example, the specification at page 41, line 13 through page 43, line 2). Based on both of these disclosures, it is clear that the NTPPHase of Masuda *et al.* is a distinct protein from CILP, although both are produced from the same mRNA. Masuda *et al.* does not disclose or suggest that a CILP is produced from cleavage of the pre-protein.

The present claims recite purified or isolated CILP peptides consisting of or comprising residues 1-682 of SEQ ID NO:2, analogs of such CILP peptides, and immunoreactive fragments of such CILP peptides (claims 1, 45, and 56, and their dependent claims). They also recite CILP

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proteins having at least 50% identity to residues 1-682 of SEQ ID NO:2 (claims 38 and 46, and their dependent claims). They further recite CILP proteins encoded by SEQ ID NO:1 (claims 49, 50, 51, and their dependent claims). As discussed above, Masuda *et al.* does not disclose or suggest a CILP peptide, much less a CILP consisting of or comprising residues 1-682 of SEQ ID NO:2, analogs of such CILP peptides, or immunoreactive fragments of such CILP peptides. Therefore, Masuda *et al.* does not anticipate claims 1, 45, or 56, or any of their dependent claims. In addition, Masuda *et al.* does not disclose or suggest a CILP protein having at least 50% identity to residues 1-682 of SEQ ID NO:2. Therefore, Masuda *et al.* does not anticipate claims 38 or 46, or any of their dependent claims. Furthermore, Masuda *et al.* does not disclose or suggest a CILP protein encoded by SEQ ID NO:1. Therefore, Masuda *et al.* does not anticipate claims 49, 50, or 51, or any of their dependent claims.

In view of the fact that Masuda *et al.* neither discloses nor suggests a CILP according to the present claims, Masuda *et al.* does not anticipate claims 1, 3-6, or 36-56. Therefore, Applicants respectfully request that the Office reconsider and withdraw the rejection of claims 1and 4-6 under 35 U.S.C. § 102(b) as anticipated by Masuda *et al.*

C. U.S. Patent No. 5,876,963

The Office rejects claims 1-7, 23, 24, and 35 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,876,963 ("the '963 patent"). (Office Action at paragraph 14.) By this Amendment, claims 2, 7, 23, 24, and 35 are cancelled, rendering the rejection moot as it applies to those claims. Applicants respectfully traverse this rejection as it applies to claims 1 and 3-6, and as it might be applied to new claims 36-56.

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Initially, Applicants submit that the '963 patent does not qualify as prior art under 35 U.S.C. § 102(b). The present application claims the benefit of the filing date of U.S. Provisional application Serial No. 60/142,054, filed July 2, 1999. The '963 patent issued March 2, 1999, which is less than one year before the filing date of U.S. Provisional application Serial No. 60/142,054. Therefore, the '963 patent does not qualify as prior art under 35 U.S.C. § 102(b). In an effort to expedite prosecution of this application, Applicants will respond to the rejection as if it had been set forth under 35 U.S.C. § 102(e).

The '963 patent discloses the human NTPPH-1 gene and encoded protein. (See the '963 patent Abstract, for example.) The NTPPH-1 protein is 1184 amino acids in length. (See SEQ ID NO:1 of the '963 patent, for example.) However, the '963 patent does not disclose or suggest a CILP protein, much less one that comprises residues 1-682 of SEQ ID NO:2 of the present application. Furthermore, the '963 patent does not disclose or suggest analogs or immunoreactive fragments of such a CILP protein. Likewise, it does not disclose or suggest CILP proteins showing at least 50% identity to such a CILP, CILP proteins encoded by SEQ ID NO:1 of the present application, or CILP proteins that are immunoreactive with antibodies raised against a CILP encoded by SEQ ID NO:1.

As discussed above in section V.B., the present claims recite purified or isolated CILP peptides consisting of or comprising residues 1-682 of SEQ ID NO:2, analogs of such CILP peptides, and immunoreactive fragments of such CILP peptides (claims 1, 45, and 56, and their dependent claims). They also recite CILP proteins having at least 50% identity to residues 1-682 of SEQ ID NO:2 (claims 38 and 46, and their dependent claims). They further recite CILP

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proteins encoded by SEQ ID NO:1 (claims 49, 50, 51, and their dependent claims). Because the '963 patent does not disclose such subject matter, the '963 patent does not anticipate the present claims.

In view of the fact that the '963 patent neither discloses nor suggests a CILP according to the present claims, the '963 patent does not anticipate claims 1, 3-6, or 36-56. Therefore, Applicants respectfully request that the Office reconsider and withdraw the rejection of claims 1and 3-6 under 35 U.S.C. § 102(b) as anticipated by the '963 patent.

D. U.S. Patent No. 6,124,095

The Office rejects claims 1-7, 23, 24, and 35 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,124,095 ("the '095 patent"). (Office Action at paragraph 15.) By this Amendment, claims 2, 7, 23, 24, and 35 are cancelled, rendering the rejection moot as it applies to those claims. Applicants respectfully traverse this rejection as it applies to claims 1 and 3-6, and as it might be applied to new claims 36-56.

The '095 patent discloses the human NTPPH-2 gene and encoded protein. (See the '095 patent Abstract, for example.) The NTPPH-2 protein is 1156 amino acids in length. (See SEQ ID NO:1 and Figure 2 of the '095 patent, for example.) However, the '095 patent does not disclose or suggest a CILP protein, much less one that comprises residues 1-682 of SEQ ID NO:2 of the present application. Furthermore, the '095 patent does not disclose or suggest analogs or immunoreactive fragments of such a CILP protein. Likewise, it does not disclose or suggest CILP proteins showing at least 50% identity to such a CILP, CILP proteins encoded by SEQ ID

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NO:1 of the present application, or CILP proteins that are immunoreactive with antibodies raised against a CILP encoded by SEQ ID NO:1.

As discussed above in sections V.B. and V.C., the present claims recite purified or isolated CILP peptides consisting of or comprising residues 1-682 of SEQ ID NO:2, analogs of such CILP peptides, and immunoreactive fragments of such CILP peptides (claims 1, 45, and 56, and their dependent claims). They also recite CILP proteins having at least 50% identity to residues 1-682 of SEQ ID NO:2 (claims 38 and 46, and their dependent claims). They further recite CILP proteins encoded by SEQ ID NO:1 (claims 49, 50, 51, and their dependent claims). Because the '095 patent does not disclose such subject matter, the '095 patent does not anticipate the present claims.

In view of the fact that the '095 patent neither discloses nor suggests a CILP according to the present claims, the '095 patent does not anticipate claims 1, 3-6, or 36-56. Therefore, Applicants respectfully request that the Office reconsider and withdraw the rejection of claims 1and 3-6 under 35 U.S.C. § 102(b) as anticipated by the '095 patent.

VI. *Rejection Under 35 U.S.C. § 103*

The Office rejects claim 35 under 35 U.S.C. § 103(a) as obvious over Lorenzo *et al.* or Masuda *et al.*, each in view of the '963 patent or the '095 patent. (Office Action at paragraph 17.) Although Applicants do not agree with the conclusion drawn by the Examiner, to expedite allowance of this application, by this Amendment, claim 35 is cancelled, rendering the rejection

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moot. Applicants expressly reserve the right to prosecute the subject matter of claim 35 in continuing applications.

VII. *Conclusion*

Applicants respectfully submit that this application is in condition for allowance. Accordingly, Applicants respectfully request that the Office reconsider and withdraw the Restriction Requirement with regard to claim 18, reconsider and withdraw the outstanding rejections, and permit this application to issue as a U.S. patent in due course. If the Examiner believes anything further is necessary in order to place this application in even better condition for allowance, he is invited to contact Applicants' undersigned representative at the telephone number or e-mail address listed below.

Please grant any extensions of time required to enter this response and charge any required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
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By: 

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Date: January 30, 2002

Attachments:
Appendix
Declaration Under 37 CFR 1.132

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APPENDIX

09/609,383

1. (Amended) A purified or isolated peptide, wherein the peptide is

a) a cartilage intermediate layer protein (CILP) comprising residues 1-682 of SEQ ID NO:2,

b) an analog of a CILP comprising residues 1-682 of SEQ ID NO:2, or

c) [a homolog of a CILP, or

d)] a fragment of a CILP[,] or [an analog of] a CILP analog, [or a homolog of a CILP,] wherein the fragment is immunoreactive with at least one antibody that is specific for a CILP comprising residues 1-682 of SEQ ID NO:2, or [an analog of] a CILP analog comprising residues 1-682 of SEQ ID NO:2[, or a homolog of a CILP]. (Support = p. 3, lines 10-11; p. 43, lines 8-13.)

3. (Amended) The peptide of claim [2] 1, wherein the peptide is a human peptide, a cow peptide, a dog peptide, or a horse peptide[a cat peptide, or a rodent peptide].

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